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NATERA, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA,

SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC.,

Defendant and Counterclaim-Plaintiff.

CASE NO. 3:21-CV-04062-EMC

NATERA'S SUPPLEMENTAL OPPOSITION TO GUARDANT'S SUPPLEMENTAL MEMORANDUM FOR SANCTIONS

REDACTED FOR PUBLIC FILING

Hearing: October 15, 2024
Time: 9:00 AM
Place: Courtroom 5, 17th Floor
Judge: Hon. Edward M. Chen

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Pursuant to this Court's Order of September 6, 2024 (Dkt. 642), Natera hereby submits its supplemental opposition to Guardant's supplemental brief. Dkt. 692.

I. THE TWO *IN CAMERA* DOCUMENTS DO NOT ENTITLE GUARDANT TO SANCTIONS

The two *in camera* documents produced September 27, 2024 do not confirm the accuracy of Guardant's motion, and they do not justify the extreme sanctions that Guardant seeks.

The first document is NRG's August 30, 2023 Dear Doctor letter. Ex. 1 at -01901. The second document is a September 15, 2023 email from Dr. Hochster about COBRA stating: "This is the short summary, and nothing else is really known outside of Guardant (unless a few people at NCI or NRG received a more complete discussion)." Ex. 2. Attached to the email was a one-page Word-document summary with the "CONFIDENTIAL." Ex. 2 at -01912. The first half of the document was public information about the trial closure. *Id*. Then, labeled as "confidential" with instructions not to discuss details with anyone else, Dr. Hochster provided a 9-line paragraph containing raw data for the treatment and observation arms of the study. *Id*. Dr. Hochster then provided a paragraph with his interpretation. *Id*. The memo is *not* the ASCO-GI abstract, does *not* refer to the abstract, and does *not* state the data was final. But Natera has since learned Dr. Hochster derived the data from a draft abstract which he had received from his Rutgers colleague, a COBRA investigator. The full significance of COBRA—including Guardant's access to and [redacted] to NRG documents—was not apparent until NRG produced its discovery. Indeed, Dr. Hochster was correct in his email that at the time "nothing else [was] really known outside of Guardant." *Id*. at -01902.

Guardant is wrong to assert that Natera repeatedly lied that Dr. Hochster never had COBRA information to move the trial date. Instead, the exchange at issue was a snippet in which Natera's counsel—while arguing to *keep* the trial date—responded to an allegation of which Natera was unaware: that Dr. Hochster had a copy of a draft ASCO-GI abstract. Given the severity of the allegations being made, it is important to provide precise quotes and context. Natera wishes it had connected the dots earlier—and regrets the impression it gave in February that Dr. Hochster did not

have early access to COBRA data—but Natera was learning in real time the facts that Guardant sat on for months. Natera had no intent to mislead the Court or delay trial.

A. Guardant Overstates Natera's Representations At The Hearings

Guardant deliberately overstates a single exchange with the Court in February 2024 about the ASCO-GI abstract—amidst extensive briefing and hearings—to claim that Natera repeatedly and "intentionally lied" to this Court to cause disruption to the Court's schedule. Not so.

Natera served Dr. Hochster's supplemental COBRA report on January 31, 2024 shortly after the ASCO-GI conference, attaching the ASCO-GI abstract and the 13-page ASCO-GI slide presentation. Dkt. 447-2 at Exs. 1 and 2. There is no dispute that the ASCO-GI conference was the first public presentation of the COBRA study with full data and analysis. With his supplemental report, Dr. Hochster also included the August 30, 2023 "Dear Doctor" letter from NRG to participating doctors (including Dr. Hochster) that reported the study's termination based on excessive false positives from Guardant's Reveal assay. *Id.* at Ex. 7. Natera never hid that Dr. Hochster knew of the COBRA closure before ASCO-GI and had patients in the study.

Guardant filed a motion to strike (Dkt. 447), which Natera opposed (Dkt. 452), and this Court held hearings on February 15 and February 24, 2024. There was supplemental letter briefing on February 29 and March 1, 2024. Dkts. 482, 484. The gravamen of Guardant's motion was that COBRA was not relevant. Dkt. 484 at 4 ("COBRA sheds no light on the specificity or PPV of Reveal."); Dkt. 447 at 4 ("the COBRA Study is irrelevant to any remaining claim in this false advertising case"). Guardant also asserted the supplemental report was untimely. Dkt. 447.

With respect to timing, at the February 15, 2024 hearing, Natera stated: "[T]his issue has been known to Guardant. It's not an ambush. And as soon as the data was publicly disseminated at the conference in January, Dr. Hochster prepared a supplemental report. He attended the conference, and his patients were participants. He encouraged his patients to participate in the study. And we provided the supplemental report to Guardant just as quickly as we could." Ex. 18 (2/15/24 Tr.) at 10:9-15. That was all true and remains so.

Natera did not seek to disrupt this Court's schedule. *Id.* at 20:1-5 ("Natera does not feel like it needs really much extra discovery, so we are prepared to go to trial as scheduled."); Dkt. 452

(Natera's 2/12/24 Opposition, which did not seek to change the trial date). Guardant took a different tack. As a reason to exclude COBRA from this case, Guardant argued that it would need "significant discovery" including "from the principal investigators." Ex. 18 (2/15/24 Tr.) at 5:1-8); *id*. at 14:25-15:8 ("we need substantial discovery"); Dkt. 630-4 (2/22/24 Tr.) 4:11-7:10 (representing Guardant needed to "depose a number of people at NRG" and others).

Guardant's argument was a pretext because as would later become clear: Guardant had massive inside access to COBRA, [redacted] *See infra*. Indeed, Guardant never sought—and largely impeded—the discovery that it implored this Court that it needed, and which ultimately led the Court to continue trial from March 2024. Dkt. 645 (Natera's Motion To Authorize NRG Deposition); Dkt. 654 (Order).

The topics of discovery and timing were discussed in the continued hearing of February 22, 2024. The exchange that Guardant relies upon for sanctions is set forth below:

> Guardant argued: "Mr. Cannon, again, said that Natera is working from the publicly available information, which the Court pointed out was disclosed in mid-January. We understand that's not true. We understand that actually Dr. Hochster, for some reason, actually had the abstract and the data at least a month and a half before, and possibly as early as November. We're going to figure all that out; but just to the extent that they're trying to say, 'Oh, they were able to pull something together in two weeks' that's just not the case. Certainly they would be able to tell the Court exactly when Mr. Hochster got the data, how he got it, but I do think that's an important point to clarify." Dkt. 630-4 at 12:8-19.
>
> Natera responded: "I also would like to note that there was an accusation that Dr. Hochster somehow had inside information. The abstract was available before the conference. The conference was in January, January 16th I believe. But there was an abstract available before the conference. So I'm certainly not aware of any sort of early access that Dr. Hochster may have had." *Id*. at 14:23-15:3.

Natera regrets the impression it left that Dr. Hochster did not have access to at least some data from COBRA. But Guardant overstates a single statement from an extensive hearing to spin up an allegation that Natera repeatedly lied to this Court. The underlying facts remain true: Dr. Hochster did not provide the ASCO-GI abstract to counsel until after it was public, did not provide the ASCO-GI presentation with the full analysis until after it was public, and, importantly, Natera could not have provided the supplemental report any earlier than it did.

On March 6, 2024, the Court ruled, stating, "Natera's delay in submitting Dr. Hochster's supplemental report was substantially justified. The COBRA study was published on January 16, 2024, and Natera submitted its expert supplemental report nearly two weeks after that date." Dkt. 493 at 5. The Court's Order did not rely on statements from the hearing about the availability of the draft abstract or any of the underlying data.

B. NRG Production Reveals Critical Facts And Guardant's Deep Involvement

The playing field on COBRA was never level. With NRG's production in July and August, 2024, Natera learned in real time a series of critical facts that Guardant had concealed.

Despite Guardant's representations to this Court that COBRA had nothing to do with CHIP filters (Dkt. 484 at 3), NRG documents revealed that [redacted] Dkt. 632-5. It is stunning that Guardant seeks ongoing damages while at the same time [redacted] plagued by false positives. Indeed, in connection with Natera's motion for reconsideration, [redacted]. Dkt. 653.

NRG's document production demonstrates that Guardant's claims of prejudice and being deprived of information about COBRA issues are pretextual. [redacted] *Compare* Ex. 4 at -63398 *with* Ex. 5 at -63471. [redacted] Ex. 6. [redacted]. Ex. 7.

C. The *In Camera* Production Does Not Warrant Sanctions

The *in camera* documents do not demonstrate any scheme to mislead this Court. Dr. Hochster provided some of the data he received from an oncology colleague to Natera's counsel—and apparently this data was circulating in the community [redacted]. Ex. 7.

Indeed, as NRG's witness testified on October 1, 2024, [redacted] Ex. 8 (Morris Tr.) at 28:4-13, 30:19-33:11.

At the time of the February 2024 hearings Natera did not know that Dr. Hochster had extracted the data in his memo from the draft abstract that he had received. Nor did Natera know of Dr. Hochster's communications with COBRA investigators beyond receiving the Dear Doctor letter. Natera wishes it had connected the dots earlier—from September 2023 onwards—and appreciated the case-changing significance of COBRA. But it did not. Natera and its counsel were learning in real time the full consequences of what occurred. As a practical matter, Natera could not have submitted a supplemental report any sooner even it was cognizant of all the facts. Dr. Hochster provided the memo with the data in confidence as the *in camera* documents reflect. The data was not final, and any report based on that limited information would have been premature. At his deposition, Dr. Hochster explained that data in draft abstracts are subject to change as the abstract becomes finalized. Ex. 17 (Hochster Tr.) at 51:9-18. Indeed, the full results and analysis were presented at ASCO-GI in January 2024.

II. GUARDANT HAS UNCLEAN HANDS AS TO HOCHSTER AND NRG

A. Guardant's Unfounded Hochster Allegations Undermine Its Request For Extreme Sanctions

Guardant's reckless and baseless accusations in open court against leading oncologist Dr. Hochster should be considered in assessing sanctions. In urging this Court to sanction Natera, Guardant accused Dr. Hochster of "going out and communicating with the primary investigators for COBRA," trying to "influence the trajectory of COBRA" and trying "to move the samples over to Signatera for Natera's benefit." Dkt. 630-2 at 12:12-19; *id.* at 13:12-14 ("[Mr. Scolnik:] [it]'s possible that without Dr. Hochster's influence, interference, that COBRA would have gone a different way."). In his August 15, 2024 letter to the Court, Dr. Hochster categorically denied the accusations. Dkt. 624 ("I did not attempt to manipulate or sabotage COBRA on anyone's behalf, including Natera. I had my own patients enrolled in the study, advocated for it within and outside my institution, and wanted it to succeed.").

The October 1, 2024 deposition of NRG on the topic of Dr. Hochster completely refuted Guardant's unwarranted accusations. NRG designated COBRA principal investigator Dr. Van Morris as the Rule 30(b)(6) witness on Dr. Hochster. Ex. 9 at 2. Dr. Morris was effusive in his praise for Dr. Hochster as a committed physician and strong advocate for COBRA:

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]"

Ex. 8 (Morris Tr.) at 27:14-15, 28:4-10; 30:19-33:11. Importantly, NRG and Dr. Morris *denied* that Dr. Hochster had "[redacted];" *denied* that Dr. Hochster had "[redacted];" and *denied* that he had "[redacted]." *Id.* at 33:19-34:6.

The false allegations against Dr. Hochster do not excuse the deficiencies in Dr. Hochster's email searches—for which he has apologized—but seeking sanctions does not justify a party saying anything it wants no matter how spurious or unsupported. There must be a good faith basis, especially when such public accusations go to the core of a physician's commitment to his patients.

B. Guardant Took A Secret *Ex Parte* "Deposition" Of NRG That Shows It Knew Its Sabotage Allegations Were Unfounded

What makes Guardant's behavior more egregious is the revelation that Guardant's attorneys met [redacted] with Dr. Morris—the NRG oncologist who exonerated Dr. Hochster in the deposition above—in a secret *ex parte* "deposition" before the July 26, 2024 hearing in which Guardant accused Dr. Hochster of sabotaging COBRA in order to urge this Court to sanction Natera.

After this Court granted Natera's motion for an order authorizing an NRG deposition (Dkt. 654), counsel for NRG emailed the parties on September 20, 2024: "I also understand that Dr. Morris was previously deposed in this case, but represented by separate counsel. Can the parties please provide me with a copy of his deposition transcript?" Ex. 10 at 4. This was news to Natera. Guardant's counsel downplayed this information asserting by email it was merely an "informal conversation." *Id.* at 1-2. It appears to have been far more than that.

At the October 1, 2024 deposition of NRG's Rule 30(b)(6) witness, Dr. Morris testified that in May 2024 he [redacted] Ex. 8 (Morris Tr.) at 172:15-174:17. When asked why he felt obligated to take such a meeting, Dr. Morris asserted privilege. *Id.* at 179:18-182:25. Dr. Morris testified that Guardant asked about Dr. Hochster. *Id.* at 177:5-14. It is still unclear to Natera the nature of the meeting—whether it was a transcribed deposition or not—but the existence of Guardant's [redacted] *ex parte* meeting is a significant event.

First, the secret May 2024 Morris "deposition" demonstrates Guardant misled the Court. In the July 26, 2024, sanctions hearing, this Court asked Guardant "what discovery did you have with the COBRA authors?" Dkt. 630-2 (7/26/24 Tr.) at 13:24-25. Guardant answered as if they were completely in the dark. *Id.* at 14:13-15:12 ("We reached out to NRG and sent them a subpoena … we received the documents just recently. It's not complete. … [W]e don't know what we don't know but it wasn't for lack of trying."). This Court has repeatedly asked Guardant about its progress in securing discovery from the COBRA investigators, and it was incumbent on Guardant to come clean that it had in fact secured such access.

Second, in the July 26, 2024, sanctions hearing, Guardant made allegations about Dr. Hochster that it knew were not true. In response to the sabotage allegations, the Court asked "Is there any evidence that the COBRA authors and those that are involved in the study acceded to his requests, recommendations?" *Id.* at 12:20-22. Guardant answered there was "circumstantial evidence" and "an evidentiary record that we can draw conclusions from[.]" *Id.* at 12:23-25. But the same attorney who accused Dr. Hochster of sabotage had discussed the same issue with NRG's Dr.

Morris—the lead COBRA investigator—in May 2024. NRG's Dr. Morris under oath completely exonerated Dr. Hochster from the accusation that he sabotaged COBRA. Guardant knew or should have known that from its [redacted] meeting or deposition with Dr. Morris.

Third, Natera was forced to limit its deposition time with Dr. Morris—it had a two-hour hard stop due to splitting time with Guardant. Ex. 11. Because of the *ex parte* "deposition" Guardant had double the time with this witness despite already having insider access to COBRA.

Guardant seeks extraordinary sanctions yet comes to Court with unclean hands. Natera respectfully requests the Court consider Guardant's own conduct in assessing its sanctions request.

III. NATERA HAD NO INTENTION TO MISLEAD THE COURT ABOUT DR. HOCHSTER'S EMAIL SEARCH

There is no dispute that Dr. Hochster did not locate and produce his emails promptly. Counsel sincerely apologizes to the Court for relying on Dr. Hochster's own explanation as to his search rather than getting to the bottom of the issue sooner. But neither Dr. Hochster nor Natera ever sought to deceive anyone or hide the truth about these emails that are of, at best, marginal relevance. Indeed, although Guardant deposed Dr. Hochster about these emails at length, neither of its two experts rebutting Dr. Hochster considered his emails at all.

The emails in question are communications with COBRA investigators—fellow oncologists—at the time of COBRA's study's termination. They reflect a concerned cancer doctor reacting in real time to a significant event in a study in which he personally enrolled patients. They also show his efforts to try to assist those same investigators to salvage some portion of the study through testing with Signatera, an assay he uses in his own practice. Indeed, NRG's Dr. Morris testified he uses Signatera in his personal practice. Ex. 8 (Morris Tr.) at 82:4-6; 85:3-10 [redacted]"). Dr. Hochster's emails reflect his dedication to patients and to advancing science, not anything improper. Indeed, Dr. Morris confirmed that in his experience with Dr. Hochster, he "[redacted]" *Id.* at 210:4-15.

Nonetheless, as Dr. Hochster recognizes and has personally informed the Court, he should have been more diligent in searching for his emails both initially in response to the subpoena, and

subsequently when he learned that Rutgers had produced emails that he had not. Dkt. 624. Dr. Hochster offered what he thought was the explanation for his failure to find the documents, which are that his email system automatically deletes emails to save space. Ex. 17 (Hochster Tr.) at 151:2-11 (describing notices he receives to this effect). Counsel conveyed this explanation to the Court and apologizes for doing so rather than independently investigating the issue sooner.

Natera and Dr. Hochster are eager for the forensic review to conclude, and have cooperated fully. The reason it remains ongoing is that Rutgers University, of its own accord, is taking understandable precautions given Guardant's demand that a third party examiner (selected by Guardant) conduct an extensive review of machines and systems containing the University's sensitive information, including HIPAA-protected patient information. As Guardant recognizes, Rutgers—not Natera—has reasonably requested to review all documents returned by Guardant's broad searches, and that process remains well underway. Indeed, Natera has offered to pay Rutgers' attorneys fees to outside counsel to accelerate the process. Ex. 12 at 1.

Guardant's attempt to pin any delay on Natera lacks merit and contradicts the September 4, 2024 stipulation (entered after all the events described in its supplemental brief) that *both* parties "have been working diligently to advance the forensic examination," and that the delays were caused by "the scope of work and the need to coordinate with Rutgers." Dkt. 640. The record bears this out. No one ever withheld that Dr. Hochster had a laptop; Dr. Hochster testified about it at his deposition. Ex. 17 (Hochster Tr.) at 150:8-13. And when Guardant requested to image *any* device that Dr. Hochster used to access his Rutgers email, as opposed to just the desktop he searched to respond to the subpoena (*id.* at 156:21-24), Natera offered Dr. Hochster's laptop for review too. Ex. 13 at 1-2. As for the laptop ownership, Rutgers needed to revisit its records to confirm. Ex. 14 at 1. Rutgers' laptop ownership meant Rutgers needed to review the machine's contents before turning it over, whereas Natera and Dr. Hochster were willing to turn over the laptop for Mr. Ackert's immediate review. Finally, Dr. Hochster's travel is a red herring, because Rutgers collected the laptop *before Dr. Hochster left*. Ex. 15 at 1.

Any delay in the process should be attributed to Guardant due to its overreaching demand that Mr. Ackert and Rutgers review irrelevant material—including Dr. Hochster's laptop. As

Rutgers ultimately confirmed, the forensic images of Dr. Hochster's desktop and laptop produced no responsive emails. Ex. 16 at 1. Nor can Guardant claim prejudice in connection with discovery from Dr. Morris. Guardant already questioned Dr. Morris about Dr. Hochster through its secret *ex parte* "deposition" on [redacted]. *Supra*. Guardant impeded a deposition of NRG, requiring Natera to seek relief from this Court. Dkt. 654. In the October 1, 2024, joint deposition, Guardant did not ask Dr. Morris a single question on Dr. Hochster's involvement with COBRA design or termination.

IV. GUARDANT IS NOT ENTITLED TO THE EXTREME SANCTIONS IT DEMANDS

When Guardant sought to exclude COBRA evidence as a sanction, this Court stated that "unless the study itself and the results that were obtained were somehow tainted as a result, and the evidence that you were seeking to get and has not been given to you would demonstrate that taint, then I don't, frankly, see a remedy that leads to the total exclusion of the COBRA study." Dkt. 630-2 (7/24/24 Tr.) at 15:20-24. The Court asked Guardant to propose a *lesser* remedy proportional to any prejudice. *Id*. at 20:23-21:2; 41:19-22. Rather than do that, Guardant seeks terminating sanctions, as well as the exclusion of COBRA. Terminating sanctions are not warranted here. Such sanctions are appropriate only in "extreme circumstances" where "the deceptive conduct is willful, in bad faith, or relates to the matters in controversy in such a way as to interfere with the rightful decision of the case." *United States v. Nat'l Med.*, 792 F.2d 906, 912 (9th Cir. 1986) (vacating and remanding trial court dismissal with prejudice). Guardant's precedent, *Anheuser-Busch. v. Nat. Beverage* , 69 F.3d 337, 348 (9th Cir. 1995) (cited Opp. at 8) is inapt because there the court dismissed claims because the party concealed critical documents for years, lied about their existence, and produced them eight months after a jury verdict. None of that has occurred here.

Likewise, COBRA should not be excluded. This Court has repeatedly ruled that it is relevant for trial. Dkts. 493 at 9, 12-13; 653, and 663 at 12-22. There is nothing new that warrants revisiting those decisions. Indeed, NRG discovery has underscored just how relevant COBRA is: Guardant's excessive false positives led it to fundamentally change its assay to improve specificity. That goes to the heart of the issues in the case.

CONCLUSION

For the foregoing reasons, Natera respectfully asks the Court to deny Guardant's Motion.

DATED: October 4, 2024

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